## REMARKS

Claims 20, 22, 23, 25-29, 31, 33, 34, 36 and 40-43 are pending in the present application. Claims 20, 22, 27, 29, 31, 33, 34, 36, and 40-43 have been amended, and new claims 45-73 have been added. No new matter is added by the amendments and new claims, and entry of the amendments is respectfully requested.

Accordingly, claims 20, 22, 23, 25-29, 31, 33, 34, 36, 40-43, and 45-73 are currently under consideration.

With respect to claim amendments and cancellations, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and have not acquiesced to any rejections and/or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Reconsideration of the application is respectfully requested in view of the following remarks. For the Examiner's convenience, Applicants' remarks are presented in the order in which they were raised in the Office Action.

### A. Support for Claim Amendments and New Claims

Claims 20 and 22 are amended to recite: "... wherein the concentration of particles is about 100 mg/mL to about 500 mg/mL of the formulation, and further wherein the hyaluronic acid or a derivative thereof is at a concentration sufficient to inject the particles through a 23-gauge or smaller bore needle."

In claims 20 and 22, the limitation "the concentration of the *polymeric matrix* is about 1 mg/mL to about 500 mg/mL of formulation" has been amended to recite: "the concentration of *particles* in the formulation is about 100 mg/mL to about 500 mg/mL." These amendments are supported by the specification at page 8, line 22 through page 9, line 4 and in Examples 3-5 and 7.

Support for the limitation "... further wherein the hyaluronic acid or a derivative thereof is at a concentration sufficient to inject the formulation through a 23-gauge or smaller bore needle" found in claims 20 and 22, as amended, is found at page 16, lines 15-18 of the specification and also in Examples 3-5, 7 and Tables 1 and 2, at pages 20-25 of the specification.

Claims 20 and 22 have been amended to recite hyaluronic acid "or a derivative thereof." Support for this amendment can be found in the original claims and throughout the specification, particularly page 4, line 25 through page 5, line 7. In this section, a "hyaluronic acid derivative" is described as having the hyaluronic acid backbone (*i.e.*, alternating glucuronide and glucosamide bonds) and one or more chemical groups (*i.e.*, functional groups) not present in naturally occurring hyaluronic acid. This would include ester, amide, and lactide derivatives, as well as pegylated and salt forms. Regarding salt forms, as disclosed in the specification on page 7, lines 10-11, "hyaluronic acid...is conveniently employed in the form of sodium hyaluronate." Further, claims 20 and 22, as amended, specify that "the hyaluronic acid or a derivative thereof in the injectable formulation is at a concentration sufficient to inject the injectable formulation through a 23-gauge or smaller bore needle." Thus, the claim further defines "the hyaluronic acid or a derivative thereof" in terms of the property to make the formulation injectable through a 23-gauge or smaller bore needle.

Support for specific polypeptides recited in amended claim 29 and new claim 59 is found on page 4, lines 1-4 and on page 10, line 8 through page 11, line 11 of the specification.

Amendments have been made to claims 27, 31, 33, 34, 36, and 40-43 to correct for antecedent basis.

New claims 45-51 are based on original claims 4, 9-11, 18, and 20. Specifically, claim 45 is supported by original claim 9; claim 46 is supported by original claim 10; claim 47 is supported by original claim 11; claim 48 is supported by original claim 18; claim 49 is supported by original claim 20; claim 50 is supported by original claim 4; and claim 51 is supported by original claim 5.

Additional support in the specification for the limitations of claim 48: "polymeric particles" (page 8, line 22 through page 9, line 19); "aqueous injection vehicle" (page 8, lines 12-13); "concentration of about 0.01 to about 3% (w/v)" (page 8, lines 2-5); and "the concentration of particles in the formulation is about 100 mg/mL to about 500 mg/mL" (page 8, line 22 through page 9, line 4 and Examples 3-5 and 7).

Support for limitations reciting needle gauge bore sizes in new claim 49 and amended claims 20 and 22, can be found in the specification on page 4, line 6-8 ("23-gauge or smaller bore"); page 16, line 16-18 ("smaller (*e.g.*, 24, 25, 26, 27, and 28 gauge) needles are preferred"); Example 3 (23-, 24-, 25-, 27-, and 28-gauge); Example 4 (23-, 24-, 25-, 27-, and 28-gauge); Example 5 (21-, 22-, 23-, 24-, 25-, 26-, and 27-gauge); and Example 7 ("using a 30-gauge needle"). New claims 61-66 and 68-73 are drawn to a method and a injectable formulation, respectively, wherein hyaluronic acid or a derivative thereof is at a concentration sufficient to inject the formulation through 23-, 24-, 25-, 26-, 27-, 28-, or 30-gauge needles respectively.

New claims 52-54 recite limitations wherein the particles are microparticles, microspheres, or particles within an average size range. Support can be found on page 6, line 7-9, and on page 14, line 2-5 of the specification.

New claims 55 and 56 recite hyaluronic acid concentration ranges which can be found on page 8, line 2-5, of the specification and in Examples 3-5 and 7.

New claims 57 and 58 recite particle concentration ranges in the injection vehicle. Support for these ranges can be found in the specification on page 9, line 2-4, and in Examples 3-5 and 7.

New claims 60 and 62 recite an injection vehicle comprising hyaluronic acid. Support for such an injection vehicle is found, for example, in original claim 6.

No new matter has been introduced by the amendments or by the new claims. Entry of the amendments and new claims is respectfully requested.

**B. Claim Rejections-35 U.S.C. §112, first paragraph**

Claims 20, 22-23, 25-29, 31, 33-34, 36 and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner points to the phrase "the concentration of the polymeric matrix is about 1 mg/mL to about 500 mg/mL of formulation" in independent claims 20 and 22.

In response, Applicants amend claims 20 and 22 to recite: "... the concentration of the particles is about 100.mg/mL to about 500 mg/mL of formulation ... ." The specification discloses formulations comprising particles with the specified limitations at page 8, line 22 through page 9, line 4 and Examples 3-5 and 7 of the specification. Therefore, Applicants respectfully request withdrawal of this ground for rejection.

**C. Claim Rejections-Obviousness Type Double Patenting**

Claims 22-23, 25-29, 31, 33-34, 36 and 43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 21-41 of co-pending application 11/614,462 (based on the amendment filed 9/20/07).

Applicants submit that because neither application has been allowed, it is currently not possible to determine whether a terminal disclaimer needs to be filed to remove the obviousness type double patenting rejection. Applicants will address this issue when claims of one or both applications are found allowable.

## CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **146392002300**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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